

FEB - 8 2005

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Carbamazepine Method for ADVIA® Modular System (IMS)™**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K042808 (leave blank)

1. Intended Use

This in vitro method is intended to quantitatively measure the antiepileptic drug carbamazepine in human serum and plasma on the Bayer ADVIA® IMS systems. Measurements of carbamazepine are used to aid in monitoring therapeutic levels of carbamazepine to ensure appropriate therapy and in the treatment of carbamazepine overdose.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Bayer Centaur Carbamazepine	07862715 (119933)	05706449 (107585)

3. Device / Method

Product Name	Reagent	Calibrator
ADVIA IMS Carbamazepine	00328780	00417120

4. Performance

A. Minimum Detectable Concentration

Method	ADVIA IMS	Centaur
MDC	0.20 µg/mL	0.25 µg/mL

B. Imprecision

ADVIA IMS	
Level µg/mL	Total CV (%)
2.62	4.6
5.63	2.6
9.19	2.5

Bayer Centaur	
Level µg/mL	Total CV(%)
3.28	9.2
5.79	8.2
9.85	8.4

C. Correlation (Y=ADVIA IMS, X = Comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx $\mu\text{g/mL}$	R	IMS Sample Range $\mu\text{g/mL}$
Serum	Centaur	48	$Y = 1.00X + 0.01$	0.80	0.988	1.2 to 17.6

D. Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Carbamazepine Concentration $\mu\text{g/mL}$	Effect (% change)
Bilirubin (unconjugated)	25	14.47	2.0
Bilirubin (conjugated)	25	14.64	-3.9
Hemoglobin	600	14.59	-0.7
Lipids (Triglycerides)	750	13.60	-8.4

E. Analytical Range

0.20 $\mu\text{g/mL}$ to carbamazepine concentration in highest calibrator (Level 6) (22.14 $\mu\text{g/mL}$).



Andres Holle
Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York, 10591 - 5097

10/4/04
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

FEB - 8 2005

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Andres Holle
Manager, Regulatory Affairs
Bayer HealthCare LLC
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591

Re: k042808
Trade/Device Name: ADVIA® IMS Carbamazepine Method
ADVIA® IMS Carbamazepine Calibrator
Regulation Number: 21 CFR 862.3645
Regulation Name: Neuroleptic drugs radioreceptor assay test system
Regulatory Class: Class II
Product Code: KLT, DKB
Dated: October 4, 2004
Received: October 13, 2004

Dear Mr. Holle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

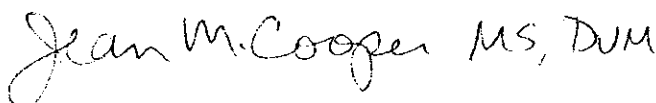
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in black ink that reads "Jean M. Cooper MS, DVM". The signature is written in a cursive, flowing style.

Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042808

Device Name: ADVIA® IMS Carbamazepine Method

Indications For Use:

The *Bayer ADVIA IMS Carbamazepine method* is for in vitro diagnostic use to measure the antiepileptic drug carbamazepine in human serum and plasma. Measurements of carbamazepine (5H-Dibenz[b,f]azepine-5-carboxamide) are used as an aid in the diagnosis and treatment of carbamazepine overdose, and in monitoring therapeutic levels of carbamazepine to ensure appropriate therapy.

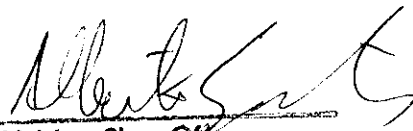
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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Indications for Use

510(k) Number (if known): K042808

Device Name: ADVIA® IMS Carbamazepine Calibrator

Indications For Use:

The *Bayer ADVIA IMS Carbamazepine calibrator* is for in vitro diagnostic use in the calibration of carbamazepine using the ADVIA® IMS system.

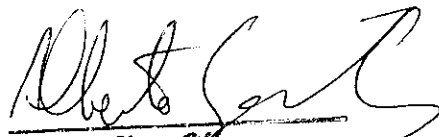
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

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